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WO 83/00087 20.01.83 Gazette 83/02(54) **PERITONEAL DIALYSES SOLUTION CONTAINING CARBOHYDRATE POLYMERS.**

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US-A-3 525 686
US-A-3 911 915
US-A-3 928 135
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US-A-4 308 255Trans, AM. Soc. Int. Organs, Vol. 18, Pages
423-428, issued 17 April 1972 Ahearn, D. J. et al.
"Addition Of aminoacids/to Peritoneal-Dialysis
fluid" Lancet, p. 812, issued 12 October 1968
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mEq/liter of chloride; and from 5 to 500 grams/liter of a metabolizable glucose polymer as described above. It is also desirable for from 30 to 40 mEq/liter of bicarbonate precursors such as one or more of lactate, acetate, malate, and/or succinate ions to be present. The bicarbonate precursor acid ions mentioned above, as well as other acid ions of the Krebs cycle may be added to also offer advantages in pH control of the peritoneal dialysis solution of this invention. The sodium or potassium salts of such ions, for example, may be used for this purpose, or the free acids. The above concentrate is preferably mixed with a conventional peritoneal dialysis solution. If mixed with water, higher ion concentrations would be desirable.

It is generally preferable for the osmolarity of the solutions of this invention to be from 272 to 700 milliosmols per liter, preferably 279 to 480 milliosmols per liter.

If amino acids or polypeptides are present in the solution, sulfhydryl-type antioxidants, for example N-acyl cysteine, may also be added to stabilize the amino acids in the peritoneal dialysis solution of this invention.

A typical solution which is contemplated for use in peritoneal dialysis is a sterile water solution containing the following: dextrose H₂O — 15 grams per liter; sodium — 132 mEq/liter; calcium — 3.4 mEq/liter; chloride — 104 mEq/liter; lactate — 37 mEq/liter; glucose polymer having a degree of polymerization of greater than 4 (Polycose®, sold by Ross) — 120 grams per liter. This solution, when sterile, may be utilized as the peritoneal dialysis solution in a conventional CAPD procedure, utilizing the techniques and equipment developed and sold by the Artificial Organs Division of Baxter Travenol Laboratories, Inc., Deerfield, Illinois, so that good ultrafiltration may take place during the peritoneal dialysis procedure; with reduced diffusion of the glucose polymer into the bloodstream of the patient. Such a solution has an ultrafiltration capability equal to or greater than a commercially available peritoneal dialysis solution containing 4.25 weight percent of dextrose.

Claims

1. A peritoneal dialysis solution which comprises a water solution of physiologically tolerable pH, having physiological salts and metabolizable starch hydrolyzate type glucose polymers having an average degree of polymerization of at least 4 in concentrations sufficient to safely effect the removal of solutes and water from a patient by peritoneal dialysis.

2. A peritoneal dialysis solution which comprises a water solution of physiologically tolerable pH and containing 116 to 140 mEq/liter of sodium, 0 to 6 mEq/liter of calcium, 100 to 144 mEq/liter of chloride, and from 5 to 200 grams per liter of a metabolizable starch hydrolyzate type glucose polymer having an average degree of polymerization of 4 to 10.

3. The solution of Claim 2 in which from 30 to 45 mEq/liter of an ion selected from lactate, malate, acetate and succinate is present.

4. The solution of Claim 3 which has a pH of 5 to 7.4.

5. The solution of Claim 4 which comprises essentially 132 mEq/liter of sodium, 3.4 mEq/liter of calcium, 104 mEq/liter of chloride, 37 mEq/liter of lactate, and 120 grams/liter of said glucose polymer.

6. The solution of Claim 1 in which essentially 0.5 to 25 grams/liter of dextrose hydrate is present.

7. The solution of Claim 1 in which from 0.5 to 25 grams/liter of an amino acid source is present.

8. A peritoneal dialysis solution which comprises a water solution of pH 5 to 7.4 and containing 116 to 140 mEq/liter of sodium, 0 to 6 mEq/liter of calcium, 100 to 144 mEq/liter of chloride and from 5 to 200 grams per liter of metabolizable starch hydrolyzate type glucose polymer having an average degree of polymerization of at least 4, plus 30 to 45 mEq/liter of an ion selected from lactate, malate, acetate and succinate, and from 0.5 to 25 grams per liter of dextrose hydrate.

9. The solution of Claim 8 in which from 0.5 to 25 grams per liter of an amino acid source is present.

Revendications

1. Solution de dialyse péritonéale qui comprend une solution aqueuse ayant un pH physiologiquement tolérable, comportant des sels physiologiques et des polymères métabolisables de glucose du type hydrolysats d'amidon ayant un degré moyen de polymérisation d'au moins 4 en concentrations suffisantes pour effectuer sûrement l'extraction de solutés et d'eau d'un patient par dialyse péritonéale.

2. Solution de dialyse péritonéale qui comprend une solution aqueuse ayant un pH physiologiquement tolérable et contenant de 116 à 140 mEq/litre de sodium, de 0 à 6 mEq/litre de calcium, 100 à 144 mEq/litre de chlorure, et de 5 à 200 g/litre d'un polymère de glucose du type hydrolysats d'amidon métabolisable ayant un degré moyen de polymérisation compris entre 4 et 10.

3. Solution suivant la revendication 2, qui comprend de 30 à 45 mEq/litre d'un ion choisi parmi les lactate, malate, acétate et succinate.

4. Solution suivant la revendication 3, qui présente un pH compris entre 5 et 7,4.

5. Solution suivant la revendication 4, qui comprend sensiblement 132 mEq/litre de sodium, 3,4 mEq/litre de calcium, 104 mEq/litre de chlorure, 37 mEq/litre de lactate, et 120 g/litre du polymère de glucose précité.

6. Solution suivant la revendication 1, qui contient sensiblement de 0,5 à 25 g/litre d'hydrate de dextrose.

7. Solution suivant la revendication 1 qui contient de 0,5 à 25 g/litre d'une source amino-acide.

8. Solution péritonéale de dialyse qui com-